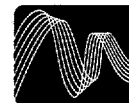


AUG 1 8 2000



K001828
MiniMed®

Section C. 510(k) Summary

In accordance with the requirements of SMDA 1990, and 21 CFR 807.92, a 510(k) Summary follows:

Submitter: MiniMed® Inc. 12744 San Fernando Rd., Sylmar, California 91342

Contact: Jennifer Lyons (818) 362-5958, Ext. 7381

Name of Device: MiniMed Paradigm™ 1.5ml Reservoir Model MMT-326

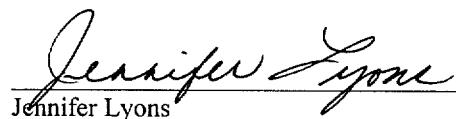
Predicate Device: MiniMed 3.0 ml Reservoir Model MMT-103

Description of the Device: The MiniMed Paradigm 1.5ml Reservoir Model MMT-326 is a single use custom reservoir system to deliver medication subcutaneously. The user-filled reservoir attaches to a medication vial for filling. The Paradigm 1.5ml Reservoir then attaches to a tubing connector on a compatible infusion set, and the reservoir is placed in an external infusion pump. The reservoir is designed for use with a MiniMed Paradigm infusion pump and Paradigm infusion sets.

The modifications which are the subject of this premarket notification have no untoward effect on the safety and effectiveness of the device.

Intended Use of the Device: The MiniMed Paradigm 1.5ml Reservoir Model MMT-326 is intended for the subcutaneous infusion of medication, including insulin, from the Paradigm family of infusion pumps and infusion sets. The reservoir is not intended for use with blood.

Comparison of the Technological Features of the New and Predicate Devices: The new device is substantially equivalent to the lawfully marketed predicate device. They differ in volume, filling mechanism, and infusion set connector.

 6/15/00
Date

Jennifer Lyons
Regulatory Affairs Specialist
MiniMed Inc.

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™Paradigm is a Trademark of MiniMed Inc.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 18 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jennifer Lyons
Regulatory Affairs Specialist
MiniMed, Incorporated
12744 San Fernando Road
Sylmar, California 91342

Re: K001828
Trade Name: Paradigm 1.5ml Reservoir MMT-326
Regulatory Class: II
Product Code: FRN
Dated: June 15, 2000
Received: June 16, 2000

Dear Ms. Lyons:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

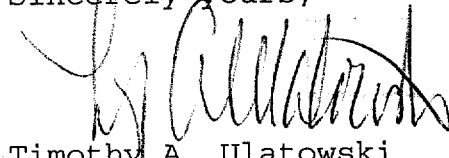
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Lyons

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center of Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

Device Name: MiniMed Paradigm 1.5ml Reservoir MMT-326

Indications for Use: The MiniMed Paradigm 1.5ml Reservoir MMT-326 is indicated for the subcutaneous infusion of medication, including insulin, from the Paradigm family of infusion pumps and infusion sets. The reservoir is not indicated for use with blood.

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001828

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